



**PRE-APPEAL BRIEF
REQUEST FOR REVIEW**

Application #	10/070,823
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First Inventor	BEYERSDORFF
Art Unit	3732
Examiner	Comstock, David C.
Docket #	P06795US00/MP

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S I R:

In response to the Office Action dated August 23, 2005, Applicants request a Pre-Appeal Brief Review of the Final Rejection in the above identified application based on the **Remarks of Attachment A**. No Amendments are being filed with this request. This request is being filed with a Notice of Appeal.

I am the Attorney of Record.

Respectfully submitted,

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ATTACHMENT A
REMARKS AND ARGUMENTS IN SUPPORT OF
PRE-APPEAL BRIEF REQUEST FOR REVIEW

This pre-appeal review is requested only with respect to the rejections under §§ 102 and/or 103 of independent claims 26, 54, 59, 63, 68, 75, 78, 81, 85, and 119. This brief is directed to the reasons why these independent claims should have been allowed by the Examiner.

The present invention relates to an instrument and method for inserting into an intervertebral space upper and lower parts which engage the surfaces of the vertebrae on either side of such space, together with a pivot element located between the parts. The instrument and the method involve first inserting the two parts into the space and then separating them to insert the pivot element between them. Claims 26, 54, 68, 75, and 81 are rejected as anticipated by either Morrison U.S. Patent No. 3,486,505 or Gau French Patent No. 2,737,656 ; claims 63, 85, and 119 are rejected as anticipated only by Morrison; claim 58 is rejected as anticipated by Bertagnoli U.S. Patent No. 5,571,109 and as not being unobvious over Morrison in view of Bertagnoli; and claim 78 is rejected as not being unobvious over Gau in view of Shapiro U.S. Patent No. 6,436,139.

Morrison describes an instrument for inserting a one piece bone graft C into a space between adjacent vertebral bodies. The graft C is pushed by a threadedly movable block 14 positioned between arms 11 which are spring biased towards each other. The arms include forward tips 12. Before insertion, the tips 12 touch each other as shown in Figure 1 to assist entry into the space between the vertebral bodies after which, as the bone graft C is moved forward, the tips 12 are pushed out by block 14 to move the vertebral bodies apart.

Gau discloses an instrument for inserting an implant between vertebral bodies. Unlike Morrison, Gau is designed for inserting an implant of the type having an upper part, a lower part, and a pivot element therebetween. However, the implant for which Gau is designed, as best shown in Figure 4, has all three of the components, the two parts and the pivot element first preassembled as one unit which is then inserted between the vertebral bodies. This patent has nothing to do with first inserting upper and lower parts and later inserting a pivot element.

Claim 1 is rejected as anticipated by both Morrison and Gau. The rejections completely ignore the environment of the invention as described in the first three lines. Such description is entitled to patentable weight since the description ties in to specific limitations set forth thereafter. The claim further recites that the two arms have at their free ends retention devices for the upper and lower parts. The Examiner erroneously reads the tips 12 of Morrison as retention devices. They retain nothing, clearly not upper and lower parts. Claim 1 also recites a longitudinal guide structure for the pivot element. Morrison shows a guide structure for a bone graft, not for a pivot element. Gau does show upper and lower arms with a retention device at the ends of the arms. However, Gau shows no structure whatsoever between the arms which could possibly be considered as any type of guide structure. The Examiner recites at page 4 of the Final Rejection that the legs of Gau "define a receiving chamber" which is capable of accommodating an implant element that could be guided longitudinally". Such supposition of what it is capable of doing is not only totally improper but totally wrong in this case.

Claim 54 is generally similar to claim 26 except that it recites the second arm more specifically as being coordinated with the first arm to insert upper and lower parts

concurrently and it recites the guide structure more specifically as being connected to and guided by the arms for spreading the arms apart and inserting the third part. As with claim 26, the Examiner has read far more into Morrison than is actually shown. The simple arms 11 and 12 with their tips 12 clearly do not anticipate the first and second arms as described in claim 54. The block 14 of Morrison touches the arms but is not guided by them and while it does cause some spreading of the arms, there are no upper and lower parts to be spread apart and no third part to be placed between the upper and lower parts. As with claim 26, Gau shows no structure whatsoever between the arms and Gau has no suggestion whatsoever for inserting upper and lower parts followed by having a guide structure cooperating with the arms to spread apart the upper and lower parts and insert a third part.

Claim 59 is rejected as anticipated by Bertagnoli and as not being unobvious over Morrison in view of Bertagnoli. Bertagnoli discloses a pair of opposed right and left guide rails 11 through which a one piece implant (see element 60 in Figure 6) is pushed into the intervertebral space. Bertagnoli lacks almost all of the elements of claim 59. It is not concerned with a three piece implant. Reading the guide rails 11 and 12 as the parallel legs, they engage a one piece implant and they are not aligned with anything on the non-existent lower part as called for in the claims. Claim 59 further recites the third part of the implant with lateral edges which engage the grooves. There is no such third part in Bertagnoli. Morrison and Bertagnoli are so totally dissimilar to each other that there is no possibility of an appropriate combination of those two references to support an obviousness rejection of claim 59.

Claim 63 is rejected as anticipated by Morrison. This claim includes many features which are not remotely present in Morrison. Morrison is not an instrument for

inserting a three piece implant having upper and lower parts and a third part. Morrison does not show arms engaging at their free ends upper and lower parts, as there are no upper and lower parts. The block 14 of Morrison might be considered as a spreader, but it does nothing to allow a third part to move between upper and lower parts. While block 14 may be considered a spreader, it cannot also be a pusher because it does not push any (non-existent) third part between the upper and lower parts.

Claim 68 was rejected as anticipated by Morrison and Gau. If the arms 11 of Morrison are the elongated structure, they neither hold nor insert an implant. Claim 68 defines a working space defined by planes through the outer surfaces of the implant and recites that the elongated structure is between those planes. Gau never relates (for example in a plan view) the outer boundaries of the implant relative to the inserting structure and hence there is no teaching that Gau meets the limitations of claim 68.

Claim 75 is rejected as anticipated by Morrison and Gau. Morrison is not concerned with a three piece implant. Its arms are not constructed or designed to hold upper and lower parts at their ends. The claim specifically recites that the parts are constructed to nest together, i.e., to overlap in the vertical direction. Morrison doesn't even show upper and lower parts, much less nesting. Gau discloses only a preassembled implant wherein the upper and lower parts never come closer together than as shown in Figure 4, i.e., they cannot ever nest.

Claim 78 is rejected as not being unobvious over Gau in view of Shapiro. In Gau, there is clearly no showing of a rotatable leg. Shapiro is a totally different structure, namely a fusion device, and it is totally improper to use Shapiro as a teaching to modify Gau so as to make one of its lower legs rotatable.

Claim 81 is rejected as anticipated by either Morrison or Gau. Morrison is not related to an instrument for inserting a three piece implant. The upper arm of Morrison cannot hold anything at its free end. There is no disclosure of a third part between the upper and lower parts. Even if the block 14 can be considered as a spreader, it is not movable along the upper and lower arms and it does not spread apart non-existent upper and lower parts; and it does not operate in the other direction to allow upper and lower parts to move towards each other. In Gau, there is no mounting structure to allow the free ends to move towards and away from each other and there is nothing whatsoever responsive to any kind of spreader.

Claim 85 is rejected as anticipated by Morrison. Morrison is not concerned with a three piece implant. Neither of its arms have any part at its free end. The lower arm 11 of Morrison does not comprise parallel legs, much less does it define a chamber between them. Morrison does not disclose a structure on the side of the legs which engages edges of a (non-existent) third part for movement therealong. The block 14 of Morrison is not mounted on legs and does not push a third part. Even if the block 14 can be considered a spreader as well as a pusher, it is not mounted on or slidable along the arms.

Claim 119 was rejected as anticipated by Morrison. Morrison does not disclose inserting an implant having upper and lower parts and an insert between them. There is no structure in Morrison for holding the upper and lower parts. There is no structure in Morrison for spreading upper and lower parts after they are in an intervertebral space. The block 14 of Morrison is for pushing a skin graft C into a space between vertebral bodies, not an insert into a space between two other parts.

END REMARKS AND ARGUMENTS